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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/915,225 | 07/25/2001 | Hannah Alexander | UVMO:011US/SLH | 5639 |

7590 04/09/2003
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EXAMINER

KATCHEVES, KONSTANTINA T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1636

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/915,225

Applicant(s)

ALEXANDER ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-33 are pending in the present application. Claims 1-31 are currently under examination.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-31 in Paper No. 7 is acknowledged. Claims 32 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Objections

Claim 14 is objected to because it appears contain a typographical error. It seems that Applicant intended the claim to read "method of claim 14" instead of "method of 14." Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-31 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claims 17-19 and 25-30 are rejected under 35 U.S.C. § 101 because the claimed invention, setting forth an incredible utility, lacks patentable utility. It is well settled patent law that all inventions seeking patent protection under U.S. Codes must be useful. The proffered

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claims 1-31 read on finding compounds for the prevention of any cancer, thereby failing to set forth a credible utility. The skilled artisan would view cancer as a group of maladies not preventable with one medicament or therapeutic regime. Claims directed to compounds preventing all cancer or finding such compounds would be seen as an incredible utility. Efforts to prevent all cancers have produced only isolated identifiable positive results.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,

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- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant's claims are directed to a method for screening agents useful in the prevention or treatment of cancer. Applicant's method comprises steps, which include contacting the amoebae, *Dictyostelium discoideum*, with a test agent and later assessing the test agent for toxicity on the cell. Applicant's method asserts that assessing the cytotoxicity of a mold to the test agent correlates to the cytotoxicity of said test agent to any and all cancer cells. Thus, Applicant asserts that therapeutics and preventatives useful in the treatment and prevention of cancer may be identified. Applicant's method seeks to identify compounds useful for any cancer. However, different types of cancer have different etiologies and manifestations of the disease.

Moreover, to identify compounds useful for treating or preventing cancer, Applicant must select an appropriate model that would translate to efficacy in at least killing mammalian cells generally and killing cells in a subject suffering from a specific cancer as well. Applicant's method uses *Dictyostelium discoideum* to screen for anticancer agents. However, Applicant has not shown any nexus between the cytotoxicity of an amoebae to the treatment and prophylaxis of cancer. The examples provided by Applicant in the specification also fail to provide a nexus between the cytotoxicity of an *Dictyostelium* and the cytotoxicity of cancer cells. Applicant has provided an expression assay measuring the expression of repB, repD and APE in *Dictyostelium* and describes a cytotoxicity assay lacking any results on pages 23-24 of the specification. Neither of these examples provides the necessary data to overcome the unpredictability of the art. At best, Applicant has provided a method to identify candidate compounds that might be

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cytotoxic to mammalian cells. However, Applicant has not identified compounds that may be useful to treat or prevent cancer. Thus, even after the screening of these compounds one of skill in the art would be unable to use them and thus would have to engage in an undue amount of experimentation to identify compounds that are useful in the prevention of treatment of cancer.

On balance, based upon the unpredictability of cancer therapy, the many different kinds of cancer, the complexity of tumor formation and growth, the breadth of the instant claims, and the deficiency in the example presented in the specification, one of skill in the art would not be able to practice the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites in steps (i), (ii) and (iii) certain qualities of the test agent. This is unclear because Applicant recites these qualities such that they are all inclusive of the others by using the word "and." Given this interpretation, it is inherently unclear how a test agent can be both cytotoxic as in step (i) and not cytotoxic as in step (ii).

Applicant's claim recites the term chemopreventative. It is unclear whether Applicant intends this word to mean a substance having therapeutic effects or substances which completely prevent and act as a prophylaxis against cancer. No definition for this term is provided in the specification to clarify this issue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
April 2, 2003


**JAMES KETTER
PRIMARY EXAMINER**